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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,552	08/02/2001	Hideakira Yokoyama	0020-4883P	4627

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BIRCH STEWART KOLASCH & BIRCH
PO BOX 747
FALLS CHURCH, VA 22040-0747

EXAMINER	
KRASS, FREDERICK F	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 06/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/890,552	YOKOYAMA ET AL.	
	Examiner	Art Unit	
	Frederick Krass	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 March 2006 (RCE Filing)*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17,20 and 22-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17, 20 and 22-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Prior Rejections

All prior rejections are withdrawn.

Obviousness Rejection

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 17, 20 and 22-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over EPA 0 239 802 in view of WO 98/17262.

The primary reference discloses the use of essential oils, including lavender, rosemary, peppermint and l-menthol, as an antimigraine agents. See the first paragraph of column 6. The prior art differs from the instant claims insofar as it teaches the administration of the oils in aroma therapies, rather than dermally.[1]

The secondary reference teaches that essential oils used in aroma therapies, *e.g.*, peppermint, lavender, rose and rosemary oils (page 4, lines 5-10) should preferably be administered dermally instead, *i.e.*, via a patch (page 7, lines 21-27) because the latter increases efficacy by preventing loss of oil to the atmosphere. See specifically page 3,

[1] The primary reference does not specifically suggest combinations of oils. It is well settled, however that is generally obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose; the idea of combining them flows logically from their having been individually taught in the prior art. In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980); In re Crockett, 279 F.2d 274, 126 USPQ 186 (CCPA 1960). Accordingly, it would have been obvious to have combined one or more of the individually disclose anti-migraine oils of the primary reference to provide a further composition to be used for the very same purpose, consonant with this reasoning. Similarly, it would have been obvious to have ascertained workable/optimal proportions for each, since such determinations have long been recognized as requiring the application of no more than routine experimentation in the art. See In re Aller, 105 USPQ 233, 235 (CCPA 1955); In re Boesch, 205 USPQ 215 (CCPA 1980); and In re Peterson, 315 F.3d 1325 (C.A. Fed 2003).

lines 10-15. The prior art differs from the instant claims insofar as it does not specifically disclose the treatment of migraine headaches, although it does clearly suggest at page 12, lines 13-18 that:

> While the invention has been described in relation to the alleviation of a number of specific conditions, there are, of course, many other conditions for which the aromatherapy dressings can be used. For example, dressings containing specific formulations may be produced for relieving anxiety, insomnia, heartburn and premenstrual tension, for detoxification, revitalizing and energizing of the both, or for improving lung capacity to name but a few.

It would have been obvious to have incorporated the anti-migraine aroma therapy oils of the primary reference into skin patches, motivated by the desire to improve efficacy while lowering oil loss as taught by the secondary reference. Furthermore, it would have been obvious in a self-evident manner to have applied those patches to the face, forehead, nape of the neck or temple (instant dependent claims 23 and 25, depending on the specific pain locus or loci present in a given patient.

Allowable Subject Matter

The examiner believes that unexpected results have been shown for the instant methods when using the following combinations of oils, in the following percentages:

1) 0.05-0.5 wt % l-menthol, and 0.05-0.5 wt % peppermint oil;

2) 0.05-0.5 wt% l-menthol and 0.05-0.5 wt % rose oil; and

3) 0.05-0.5 wt% l-menthol and 0.05- 0.5 wt% lavender oil.

See the formulations set forth in Tables 1 and 2 at pages 9 and 10, respectively, of the instant specification, as well as the data demonstrating unexpected therapeutic efficacy for same in Table 3 at page 12.

Claims limited to the dermal treatment of migraine with these particular combinations and percentages would be allowable. Currently, however, none of the instant claims are seen to be commensurate in scope with those results, since they either fail to specify particular percentages (claim 20), or include oils for which no showing of unexpected results has been made (juniper and rosemary oils, respectively, as recited by instant claims 17 and 26).

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frederick Krass whose telephone number is (571) 272-0580. The examiner can normally be reached on Monday-Friday from 9:30AM to 6:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marschel Ardin, can be reached at (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For

more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frederick Krass
Primary Examiner
Art Unit 1614